JUDGE CASTEL

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13 CIV 1395

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Plaintiff,

v.

HOSPIRA WORLDWIDE, INC. and HOSPIRA, INC.,

Defendants.

No. 13 CIV ( )

COMPLAINT

Plaintiff GlaxoSmithKline Biologicals, S.A. ("GSK"), by its attorneys, Debevoise & Plimpton LLP, for its complaint against Defendants Hospira Worldwide, Inc. and Hospira, Inc. (together, "Hospira") alleges as follows:

Nature Of The Action

1. This action arises from Hospira's material breaches and unilateral termination of a contract, dated as of December 31, 2010, entered into by GSK and Hospira, for the production and manufacture of an influenza vaccine product, which was to be sold and distributed across the United States.

2. Under the contract, Hospira agreed to manufacture an influenza vaccine product that would be in compliance with the contract's quality requirements, in accordance with current

good manufacturing practices ("cGMP"), appropriate for regulatory submission by the end of 2011, and "otherwise acceptable to GSK at its sole discretion."

3. Hospira failed to meet any of these obligations. The vaccine product produced by Hospira (far behind schedule) contained numerous quality problems, was not in accordance with cGMP, was not appropriate for regulatory submission, and was not acceptable to GSK. GSK frequently notified Hospira of its failures to perform under the contract, and, on multiple occasions, Hospira itself issued written declarations acknowledging its failures to perform under the contract. In the face of Hospira's repeated failures, GSK attempted to work with Hospira to help Hospira come into compliance with its contractual obligations. But despite GSK's efforts to help Hospira comply with its obligations and salvage the project, Hospira was never able to meet its contractual obligations.

4. On March 22, 2012, after repeatedly and continuously failing to perform, Hospira simply gave up. On that day, Hospira informed GSK that Hospira was unilaterally terminating the contract, more than three years before the end of the contract's term in December 2015. Hospira confirmed its unilateral termination in writing and subsequent conversations.

5. At the time that Hospira unilaterally terminated and breached the contract, Hospira had failed to deliver a vaccine product acceptable to GSK or produce a product in compliance with the contract's quality requirements and in accordance with cGMP. Hospira also had failed to meet the contract's project deadlines and deliver a product ready for regulatory submission by year-end 2011.

6. Hospira's actions in this case are not isolated events. The FDA has sent multiple warning letters to Hospira for failing to comply with cGMP and failing to address other quality and compliance issues. Federal regulators have additionally forced Hospira to issue recalls of its

products and multiple newspapers have recently reported that Hospira faces systemic problems at its manufacturing facilities. Indeed, even one of Hospira's own executives acknowledged that the company had become "a little lazy" and was "skating behind the puck." As Hospira's comments reveal, Hospira faces critical quality problems in its manufacturing processes.

7. Prior to Hospira's unilateral termination of the contract, GSK had, in reliance on Hospira's contractual promises, devoted over a year's worth of time and tens of millions of dollars in resources in order to perform under the contract.

8. GSK has now sustained substantial damages as a direct and proximate cause of Hospira's material breaches and unilateral termination. GSK's damages, which were a foreseeable and probable consequence of Hospira's breaches, exceed $25 million.

Parties

9. GlaxoSmithKline Biologicals, S.A. is a foreign corporation, organized and existing under the laws of Belgium, with its principal place of business in Rixensart, Belgium. GSK is a global healthcare company that researches and develops innovative vaccines for distribution around the world.

10. Defendant Hospira Worldwide, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business in Lake Forest, Illinois. Hospira Worldwide, Inc. is a party to, and breached its obligations under, the Agreement at issue in this case. Hospira Worldwide, Inc. is a wholly-owned subsidiary of Hospira, Inc.

11. Defendant Hospira, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business in Lake Forest, Illinois. Hospira, Inc. is a worldwide provider of injectable drugs, infusion technologies, and other pharmaceutical products. Hospira, Inc. is a party to, and breached its obligations under, certain individually executed contracts which were attached as schedules to, and form a part of, the overall

Agreement at issue in this case. Moreover, Hospira, Inc. manifested its intent to be bound by the Agreement because, among other things, a Hospira, Inc. employee signed the agreement, Hospira, Inc. employees controlled the negotiation of the Agreement, and Hospira, Inc. is the signatory to certain schedules incorporated within and forming a part of the Agreement, including Schedules 5 and 7. On information and belief, Hospira, Inc. may also be held liable as the alter ego of Hospira Worldwide, Inc.

Jurisdiction and Venue

12. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332 because there is complete diversity between the parties and because the amount in controversy exceeds $75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over Hospira, Inc. and Hospira Worldwide, Inc. pursuant to N.Y. Civ. Prac. L & R. §§ 301 & 302. Hospira, Inc. has regularly transacted and done business in the State of New York and in this District, is authorized to do business in New York, owns real property and maintains branch offices in the State of New York, has substantial and continuous contacts with the State of New York and this District, and has purposefully availed itself of the rights and benefits of New York law. Hospira Worldwide, Inc. has regularly transacted and done business in the State of New York and in this District, is authorized to do business in New York, has substantial and continuous contacts with the State of New York and this District, and has purposefully availed itself of the rights and benefits of New York law.

14. Venue is proper in this District pursuant to 28 U.S.C. § 1391, because defendants are corporations subject to personal jurisdiction in this District, and, therefore, are deemed residents of this District pursuant to 28 U.S.C. § 1391(c).

Facts

Hospira's Obligations under the Agreement

15. GSK and Hospira entered into a Toll Manufacturing Agreement (the "Agreement"), dated as of December 31, 2010, for the production and manufacture of an influenza vaccine product, which was to be sold and distributed across the United States and in the State of New York. The Agreement encompassed certain schedules, some of which were themselves individually executed contracts between the parties, which formed a part of the overall agreement between the parties. Under Section 27 of the Agreement, the parties agreed that the Agreement would remain in full force and effect until December 31, 2015.

16. Pursuant to Section 8 of the Agreement, GSK supplied Hospira with the raw materials for the production of the vaccine product.

17. Under Section 6 of the Agreement, Hospira agreed to use the raw materials supplied by GSK to produce batches of the vaccine product ("Validation Batches") in compliance with the Agreement's quality requirements and "otherwise acceptable to GSK at its sole discretion." Under the same section, Hospira also agreed to manufacture a "Vaccine Product . . . in accordance with the Terms of this Agreement, Good Manufacturing Practice, . . . [and] the Quality Agreement [which was an individually executed contract attached as Schedule 7 to the Agreement]."

18. The parties agreed to a broad definition of the term "Vaccine Product" in the Agreement, reflecting the parties' intent to leave open the precise nature and composition of the product so as to ensure its acceptability to GSK and compliance with the Agreement's quality standards. Under Section 1.47, Vaccine Product "means the GSK influenza vaccine product which includes the Bulk [(i.e. raw materials)] filled and finished by Hospira." Here, Hospira agreed that the Vaccine Product it bound itself to produce could change over time in order for

Hospira to produce a Vaccine Product acceptable to GSK and in accordance with the Agreement's quality standards.

19. The parties additionally agreed to a clear timetable for project deadlines. According to Schedule 3 of the Agreement, Hospira agreed that all Validation Batches would be ready for regulatory filing in 2011.

20. On September 15, 2011, Hospira and GSK executed the Quality Agreement (incorporated into the Agreement as Schedule 7), which sets out detailed procedures and technical information for production under the Agreement. In particular, Section 22 of the Quality Agreement provides:

> Hospira shall conduct and maintain all [validation] necessary to ensure processes, facilities and systems used for the Product manufacturing meet the requirements of GMP, [regulatory requirements] and the PTS [Product Transfer Specification]. This includes, but is not limited to, manufacturing processes, cleaning and sanitization, GMP related computer systems, critical facilities . . . and test methods.

Section 15 of the Quality Agreement additionally obligates Hospira to manufacture the Product "in strict accordance with cGMP and [regulatory requirements] . . . ."

Hospira's Failure to Perform under the Agreement

21. Hospira never met its obligations under Section 6 of the Agreement to produce Validation Batches or a Vaccine Product acceptable to GSK or to produce a Vaccine Product in compliance with the Agreement's quality requirements, in accordance with cGMP, and appropriate for regulatory submission by the end of 2011.

22. Rather, in breach of Section 6, Section 24, and Schedule 3 of the Agreement, Section 22 of the Quality Agreement, and the Agreement's additional provisions on quality requirements, the Validation Batches and Vaccine Product produced by Hospira contained numerous quality problems, were not in accordance with cGMP, and were never ready for

regulatory submission. Hospira's product, *inter alia*, contained unacceptable inconsistencies, was adulterated with silicone, did not adequately mitigate against contamination risks, had invalid cleaning runs suffering from critical deviations, and generally failed to satisfy the Agreement's validation and other quality requirements.

23. Hospira also failed to meet the Agreement's project deadlines. Under Section 3 of the Agreement, Hospira agreed to submit to GSK a product ready for regulatory filing by 2011. To date, however, Hospira has failed to do so.

24. Hospira's failures to perform under the Agreement are well documented. Hospira itself has drafted and signed written declarations admitting to its failures to perform. On November 30, 2011, for example, Hospira admitted that its validation results were "invalid" and "not acceptable for commercial use." On December 6, 2011, Hospira again admitted that its validation results were "invalid." Even as late as February 23, 2012, Hospira admitted that its product was fraught with "errors" and "unacceptable for GSK."

25. GSK consistently notified Hospira of its failures to perform under the Agreement. On September 7, 2011, for example, GSK informed Hospira that it had failed to produce successful Validation Batches acceptable to GSK as required by the Agreement.

26. Moreover, in October 2011, GSK conducted and distributed to Hospira an audit report detailing Hospira's production failures under the Agreement. The audit report found, *inter alia*, that Hospira's validation process was incomplete and insufficient, that Hospira's monitoring failed adequately to mitigate against contamination risks, and that Hospira had not met appropriate quality standards.

27. GSK additionally provided notice to Hospira of its failures to perform in written memoranda signed by Hospira in November 2011, December 2011, and February 2012. GSK

also held weekly meetings with Hospira to discuss project status and consistently informed Hospira at these meetings that it had failed to meet its obligations.

28. While GSK consistently notified Hospira of its failures to perform under the Agreement, GSK also went to great lengths to work with Hospira to try to help Hospira produce acceptable Validation Batches and a Vaccine Product ready for regulatory submission and commercialization. In an October 28, 2011 meeting, for example, GSK addressed a number of Hospira's major quality failures and developed remediation and mitigation strategies to try to put the project back on course. On March 16 and March 17, 2012, GSK circulated to Hospira a proposed plan for product development in the hopes that Hospira could complete successful Validation Batches and submit the product for regulatory filing by October 2012.

29. Hospira, however, continued to fail to perform under the Agreement and at no point met its obligations to produce a product in accordance with the terms of the Agreement.

Hospira's Unilateral Termination of the Agreement

30. On March 22, 2012, more than three years before the end of the Agreement's term in December 2015, Hospira notified GSK that it intended to terminate the Agreement. Hospira's decision to terminate the Agreement on March 22, 2012 was confirmed by an email from Hospira later that day and by a conversation between the parties on March 30, 2012.

31. On April 2, 2012, GSK informed Hospira in writing that its decision to terminate the Agreement constituted a material breach of the contract.

32. On April 4, 2012, Hospira acknowledged by email to GSK that Hospira considered the Agreement terminated.

33. To date, Hospira has failed to remedy its breach.

First Cause of Action
(Breach of Contract)

34. GSK repeats and realleges each and every allegation set forth above.

35. The Agreement is a valid and enforceable contract between GSK and Hospira, made for valid consideration, and governed by the laws of the State of New York.

36. GSK has in good faith performed its obligations under the Agreement.

37. Hospira's failure to produce Vaccine Batches and a Vaccine Product in compliance with the Agreement's quality requirements, in accordance with current good manufacturing practices ("cGMP"), appropriate for regulatory submission by the end of 2011, and otherwise acceptable to GSK constitutes a material breach of contract.

38. Hospira's unilateral termination of the Agreement on March 22, 2012 constitutes a material breach of contract.

39. Hospira has committed material breaches of the Agreement and specifically has violated *inter alia* Sections 6, 24, 27, Schedule 3, Schedule 5, and Schedule 7 of the Agreement.

40. Hospira has failed to remedy its breaches.

41. By virtue of the foregoing, GSK is entitled to (a) money damages against Hospira equal to GSK's losses in an amount exceeding $25 million; (b) interest on its damages claim; and (c) costs, expenses, and attorney's fees, pursuant to Sections 1.27 and 24.9 of the Agreement.

Second Cause of Action
(Promissory Estoppel)

42. GSK repeats and realleges the allegations set forth above.

43. Hospira promised to produce a vaccine product in accordance with industry standards which GSK could submit to regulatory authorities and market in the U.S. and in the State of New York.

44. Hospira made this promise to GSK with the expectation that GSK would rely upon this promise.

45. GSK reasonably and foreseeably relied upon Hospira's promise to produce a vaccine product which GSK could submit to regulatory authorities and market in the U.S. and in the State of New York.

46. Because of its reliance on the agreement with Hospira, GSK did not contract with any other parties to produce a vaccine product.

47. As a direct and proximate result of Hospira's promise to accept GSK's offer, GSK suffered damages including, but not limited to, costs incurred on the raw materials for the vaccine product, components for the vaccine product, capital expenditures, and production equipment.

48. Permitting Hospira to avoid its obligations to perform would unjustly enrich Hospira and unfairly prejudice GSK.

49. By virtue of the foregoing, GSK is entitled to (a) money damages against Hospira equal to GSK's losses in an amount exceeding $25 million; (b) interest on its damages claim; and (c) costs, expenses, and attorney's fees.

Third Cause of Action
(Quantum Meruit and Unjust Enrichment)

50. GSK repeats and realleges the allegations set forth above.

51. GSK performed its services in good faith and gave Hospira, without charge, raw materials worth tens of millions of dollars so that Hospira could manufacture a vaccine product which GSK could submit to regulatory authorities and market in the U.S. and in the State of New York.

52. GSK additionally spent nearly a year and a half working with Hospira to try to manufacture the vaccine product.

53. For nearly a year and a half, Hospira accepted these services, materials, and equipment.

54. In consideration for these services, materials, and equipment, GSK expected Hospira to produce a vaccine product which GSK could submit to regulatory authorities and market in the U.S. and in the State of New York.

55. To date, Hospira has failed to deliver to GSK a vaccine product in accordance with industry standards which GSK can submit to regulatory authorities or market in the U.S. and in the State of New York.

56. Hospira has therefore been enriched and received benefits at GSK's expense.

57. By virtue of the foregoing, GSK is entitled to a reasonable value of its services which amount to (a) money damages against Hospira equal to GSK's losses in an amount exceeding $25 million; (b) interest on its damages claim; and (c) costs, expenses, and attorney's fees.

58. Equity and good conscience require restitution for GSK and militate against permitting Hospira to retain what GSK seeks to recover.

Reservation of Rights

59. GSK reserves the right to amend this Complaint.

Prayer for Relief

WHEREFORE, plaintiff GSK respectfully requests that the Court award GSK money damages in an amount equal to GSK's losses; award GSK all interest as provided by law,

including prejudgment interest; award GSK its attorneys' fees, disbursements and costs; and award GSK such other and further relief as this Court shall deem just and proper.

Dated: New York, New York
February 28, 2013

Respectfully submitted,

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By: _____

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